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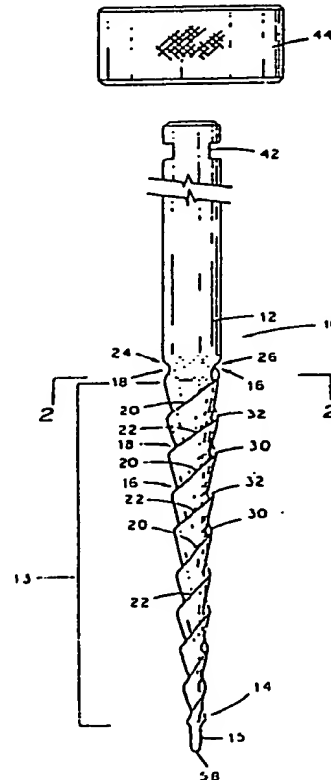
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/US81/01016 (22) International Filing Date: 30 July 1981 (30.07.81) (31) Priority Application Number: 263,406 (32) Priority Date: 14 May 1981 (14.05.81) (33) Priority Country: US (71) Applicant: INVENTIVE TECHNOLOGY INTERNATIONAL, INC. [US/US]; 71 Wilson Avenue, Johnson City, TN 37601 (US). (72) Inventor: McSPADDEN, John, Thomas ; 71 Wilson Avenue, Johnson City, TN 37601 (US). (74) Agents: LUEDEKA, Edwin, Miller et al.; Luedeka & Fitch, 1230 Park National Bank Building, Knoxville, TN 37902 (US).			(81) Designated States: AT (European patent), AU, BR, CH (European patent), DE (European patent), DK, FR (European patent), GB (European patent), JP, SE (European patent). Published With international search report.

(54) Title: DENTAL FILE

(57) Abstract

A dental file which is useful in endodontia for removing dead or damaged tissue from a curved tooth root canal while minimizing the tendency to form ledges and slits. The file has a flexible tapered shank (12) which has a cutting surface (20, 22) on its periphery and a pilot (15) projecting from the tapered end of the file for guiding the shank (12) along the curved root canal preventing the cutting surface (20, 22) near the end of the shank (12) from gouging into the wall of the curved root canal or penetrating too far through the apical foramen of the root canal. A set of dental files is also disclosed in which the files in the set increase in diameter from one file to the next larger file in the set. In such a set the diameter of the pilot on each file is substantially the same for all files in the set.



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DENTAL FILETechnical Field:

The present invention relates to the field of dental instruments and more particularly to files used in endodontia to remove dead or damaged material from a tooth root canal preparatory to filling the root canal.

Background Art:

In endodontia, one of the most delicate and precise operations is the removal of dead or damaged tissue from a tooth root canal, and the cleaning of the walls of the root canal before filling of the root canal with an appropriate material. Care must be taken not to cut too deeply into the walls of the root canal and unduly damaging the tooth structure, and not to penetrate too far into the apical foramen of the root canal unduly increasing its size and penetrating into the tooth supporting tissue.

Instruments called dental files are used to remove tissue from a root canal and properly clean the walls of the root canal. Typical dental files have a tapered shank with a working or cutting surface which cuts the tissue to be removed from the root canal as the file is moved in the root canal. Typical of these files is the so-called Hedstrom file. These files are made by machine grinding flutes into tapered, rod shaped, metal stock in a spiral fashion which increases in diameter from the tip to the shank. These dental files can be manually manipulated by means of a hand grip affixed to one end of the file shank, or the shank can be fitted into a power driven dental drill chuck or handpiece. The files cut on the pulling stroke.

Typically, tooth root canals are not straight but are curved. As a dental file is moved in a curved tooth root canal, force vectors are exerted on the working surface near the end of the shank of the dental file by the tooth structure within the root canal and by the manipulating means. These force vectors create a force couple which bends the dental file into an arcuate configuration generally conforming to the



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curvature of the root canal. The component of this force couple exerted on the working surface of the shank is typically applied near the tapered end of the shank. Due to the modulus of elasticity of the material from which the dental file is fabricated, the dental file has a natural disposition to retain a straight configuration with the result that the end of the shank of the dental file exerts a counter force on the tooth structure against the concave surface of the curved root canal equal to the force vector on the end of the shank which causes it to bend. This counter-force will increase the cutting action of the working surface of the shank of the dental file and particularly of the end of the shank against the concave surface of the root canal. Under some conditions the dental file can cut too deeply into, or gouge the concave wall of the curved root canal forming what is sometimes referred to as a ledge, or even perforate through the tooth structure, and unduly damage the tooth structure.

The procedure, generally, is to start the removal operation with a small diameter file and to incrementally progress to larger diameter files until all of the dead or damaged material has been removed from the root canal and the walls of the root canal are properly cleaned. Due to the formation of a gouge or ledge in the concave wall of the curved root canal, each succeeding larger file will move into the ledge created by the previous file and will be bent to a lesser extent. Thus, the curvature of the curved root canal will be continuously distorted or straightened from its original curvature. It is even possible that the ledge will be increased in size as succeeding larger files are used to such an extent that a file penetrates through the tooth structure resulting in undue damage to the tooth structure. Furthermore, under some conditions the dental files can penetrate the apical foramen of the root canal increasing the size of the apical foramen as succeeding larger diameter files are used causing undue damage to the tooth structure and possibly the tooth supporting tissue.

Disclosure of Invention:

Accordingly, it is the object of this invention to



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provide a dental file which will more truly follow the natural curvature of a tooth root canal and which will minimize the formation of ledges and minimize the chances of perforating the tooth structure. This is accomplished by providing a dental file having a shank tapered at least part of its length and having cutting means formed in at least a portion of the tapered length of the shank. At the tapered end of the shank a generally cylindrical, non-cutting pilot is provided, which has a generally blunt end which projects coaxially from the tapered end of the shank. The pilot has a length of from greater than about 1.0 mm to about 3.0 mm.

Further, the objects of the invention are also accomplished by the provision of a set of dental files of increasingly greater diameter from one file to the next larger file in the set. In such a set the pilot is of substantially the same dimensions for each file in the set and the diameter of the pilot on each file is smaller than the diameter of the tapered shank of the smallest file in the set measured at about 1.0 mm from the tapered end of the shank.

In connection with a set of files having widely varying diameters, the set may be broken into two portions, the smaller having a pilot of one diameter and the larger portion having a pilot of slightly larger diameter.

Brief Description of Invention:

FIGURE 1 illustrates a dental file embodying various features of the present invention, the proportions of the dental file being somewhat distorted to clearly show structural features;

FIGURE 2 is an enlarged cross-section taken in the direction of arrows 2-2 of FIGURE 1;

FIGURE 3 is an enlarged view of an end portion of a file of one size, embodying various features of the present invention;

FIGURE 4 is an enlarged view of an end portion of a file similar to that shown in FIGURE 3, but of a larger size;

FIGURE 5 illustrates a heretofore known file in use;

FIGURE 6 illustrates the file of FIGURE 1 in use;

FIGURE 7 is an enlarged view of the end portion of



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the file of FIGURE 4 in use; and,

FIGURE 8 diagrammatically illustrates a root canal cleaned by a set of files of the present invention.

Best Modes for Carrying Out the Invention:

5 The illustrated embodiment shows a file particularly adapted for removing tissue from the root canal of a tooth which comprises a flexible shank tapered along at least part of its length and having a cutting surface formed in at least a portion of its tapered length and a generally cylindrical smooth walled pilot having a generally blunt end projecting coaxially from the tapered end of the shank.

10 As illustrated, the cutting surface formed in the shank comprises at least two oppositely disposed continuous helical flutes formed in at least a portion of the tapered length of the shank defining at least two oppositely disposed helical cutting edges. However, it should be clearly understood that the present invention can be used with a dental file formed with another type of cutting surface. For example, the present invention can be used with a file having its shank formed with diamond chips, or a dental file having one helical flute and cutting edge as the Hedstrom file.

20 Now with reference to FIGURES 1, 2 and 3, the dental file, generally denoted as the numeral 10, has a flexible shank 12 tapered along at least a portion of its length 13 to a tapered end 14 and a pilot 15 projecting coaxially from the tapered end 14. A portion of the shank above the tapered portion is illustrated as being substantially cylindrical. Two continuous helical flutes 16 and 18 are formed in at least a portion 14 of the tapered length of the shank 12 defining two helical cutting edges 20 and 22 respectively.

30 The two continuous helical flutes are a first flute 16 and a second flute 18. The second flute 18 originates at a region, denoted as the numeral 24, 180° around the circumference of the shank 12 from the origination region, denoted as the numeral 26, of the first flute 16. Each of these flutes 16 and 18 is a continuous flute from its point of origin to the tapered end 14 of the shank 12.



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The first continuous helical flute 16 defines a first sharp, continuous, helical cutting edge 20 and the second continuous helical flute 18 defines a second sharp, continuous, helical cutting edge 22. Each of these cutting edges 20 and 22 is generally directed upwardly or away from the tapered end 14 of the shank 12 as will be described below. Preferably, the cutting edges 20 and 22 number from about 0.1 to about 5.0 per millimeter of shank length.

As illustrated, the flutes 16 and 18 follow a right-handed twist and have a right-handed cutting direction. However, it is contemplated that the flutes 16 and 18 could follow a left-handed twist and that the cutting edges 20 and 22 would have a left-handed cutting direction.

As mentioned above, the cutting edges 20 and 22 are generally directed upwardly or away from the tapered end 14 of the shank 12. To this end, each of the first and second flutes 16 and 18 is undercut. The first flute 16 is undercut in the region, generally denoted as the numeral 30, immediately adjacent the cutting edge 20 to form what is sometimes referred to as a positive rake angle flute. The second flute 18 is also undercut in the region generally denoted as the numeral 32, immediately adjacent the second cutting edge 22 to form the positive rake angle flute.

With particular attention to FIGURE 2, the first and second flutes 16 and 18 cooperate to define a web area 34 therebetween. The web area 34 has a continuous radial web clearance from the first cutting edge 20, generally denoted by the numeral 36A, and a continuous radial web clearance, generally denoted as the numeral 36B, from the second cutting edge 22.

As can be best seen in FIGURES 1 and 2, the wall 38 of the web 34 formed by the first flute 16 slopes away from the first cutting edge 20 generally inwardly of the shank 12 in a direction toward the tapered end 14 of the shank 12. As illustrated, the wall 38 immediately slopes away from the cutting edge 20. Similarly, the wall 40 of the web 34 formed by the second flute 18 slopes away from the second cutting edge 22 generally inwardly of the shank 12 in a direction toward the tapered end 14 of the shank 12. As illustrated,



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the wall 40 immediately slopes away from the cutting edge 22.

The first cutting edge 20 is defined by the undercut region 30 and the sloping wall 38 of the web 34 and is, thus, a very sharp edge with minimal or virtually no land area about the outside circumference of the first cutting edge 20. The second cutting edge 22 is also similarly defined by the undercut region 32 and the sloping wall 40 of the web 34 and is, thus, a very sharp edge with a minimal or virtually no land area about the outside circumference of the second cutting edge 22.

Referring to FIGURE 1, the end of the cylindrical portion of the shank 12 above the tapered length 13 is illustrated as being formed with two notches 42 so that the dental file can be adapted for use in a power driven dental drill apparatus or hand piece. Alternatively, a handle 44 is adapted to be attached to the cylindrical end of the shank 12 so that the file 10 can be used manually.

A better understanding of the shortcomings of the heretofore known dental files will be had by referring to FIGURE 5 during the following discussion. FIGURE 5 illustrates a heretofore known dental file 46 in use in a curved root canal 48. As illustrated, the heretofore known dental file 46 has a shank 50 terminating at an end 51, a working or cutting surface 52 formed in the shank 50 for cutting tissue from the root canal 48, and manipulating means 56 at the other end of the shank.

As was generally discussed above, as the dental file 46 is moved in the curved root canal a force is exerted on the shank 50 near it's end 51 by the tooth structure within the curved root canal 48 and on the manipulating means 56 by the operator. These forces create a force couple which bends the shank into an arcuate configuration generally conforming to the curvature of the root canal 48. The component of the shank bending couple exerted on the shank is applied against the working surface 52 near the end 51 of the file shank and is denoted as force vector "A". The component of the shank bending couple exerted on the manipulating end 56 by the operator is a secondary force couple denoted by the force vectors "B".



7.

Because of the modulus of elasticity of the material from which the file shank is fabricated, the file shank 50 will exert an equal and opposite force, denoted as force vector "C", to the force vector "A" against the concave wall of the curved root canal 48. This counter-force "C" will force the cutting surface 52 near the end 51 of the shank 50 against the concave wall of the root canal and increase the cutting action of the cutting surface 52 of the file shank against the concave wall of the curved root canal. Heretofore known dental files could, therefore, cut too deeply into the concave wall creating a slit or ledge denoted as the letter "D". As the ledge becomes deeper with succeeding larger files, it could even perforate the tooth structure. As succeeding larger diameter files are used, there is a danger of penetrating through the apical foramen, denoted by the letter "E", of the root canal increasing the size of the apical foramen "E" causing undue damage to the tooth structure and injury to the tooth supporting tissue.

Returning to a discussion of the present invention, with reference to FIGURES 1, 3, 4, 6 and 7, the pilot 15 has a generally cylindrical smooth wall and is integrally formed with and coaxially projects from the tapered end 14 of the shank 12. The end 58 of the pilot 15 has no surfaces capable of cutting and is illustrated as being rounded so that the pilot 15 will not dig into or otherwise cut the tooth structure surrounding the curved root canal 48. It should be clearly understood that other blunt shapes will also work. The pilot 15 is sized so that it will contact the concave wall of a curved root canal 48 before the cutting edges 20 and 22 near the tapered end 14 of the shank 12 adjacent the pilot 15 contact the concave wall of the root canal 48 (as can be seen in FIGURES 6 and 7). Thus, the pilot 15 guides the fluted length 13 of the shank along the curved path of the curved root canal 48 and relieves the cutting edges 20 and 22 near the end 14 of the shank 12 adjacent the pilot 15 of the force exerted by the wall of the root canal which causes the shank 12 to bend. The relative sizing of the pilot 15 and tapered end 14 of the shank results in the force vector "A" applied to the shank 12 being exerted on the pilot 15.



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and not on the cutting edges 20 and 22 of the shank near the end of the shank. Therefore, the equal and opposite force "C" will be applied by the pilot 15 against the concave wall of the root canal 48. To this end, it has been found that for dental files 10 having a shank diameter, measured at about 1 mm above the tapered end 14, of from about .30 mm to about .40 mm, the pilot 15 should have a diameter of about .25 mm and a length greater than about 1 mm and less than about 3 mm measured to the first cutting edge 20 and 22 adjacent the tapered end 14. For dental files 10 having a diameter, measured at about 1 mm above the tapered end 14, of from about .45 mm and larger, the pilot 15 should have a diameter of about .35 mm and a length greater than about 1 mm and less than about 3 mm measured from the first cutting edge 20 and 22 adjacent the tapered end 14.

The present invention also provides a set of files 10, as described above, comprising a first plurality of files 10 having tapered shanks 12 which incrementally increase in diameter from one file to the next larger file with the dimensions of the pilot 15 being substantially the same for each file of the first plurality of files, and a second plurality of files having tapered shanks 12 which incrementally increase in diameter from one file to the next larger file with the dimensions of the pilot 15 being substantially the same for each file of the second plurality of files. The smallest file (see FIGURE 4) of the second plurality of files is larger in diameter than the largest file (see FIGURE 3) of the first plurality. The pilot 15 of the second plurality of files is larger in diameter than the pilot 15 of the first plurality of files. Preferably, the diameter of the pilot 15 of the second plurality of files is smaller in diameter than the diameter of the shank 12 of the largest file of the first plurality of files as measured at about 1 mm above the tapered end 14 of the largest file of the first plurality of files. Preferably, however, the pilots of the second plurality of files are of substantially the same length as the pilots of the first plurality of files.

It has been determined that a preferred set of dental files have the following dimensions:



9.

SET

Fluted Length of Shank	Diam. of Shank 1mm Above Tapered End	Diam. of Shank 14 mm Above Tapered End	Length of Pilot	Diam. of Pilot
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FIRST PLURALITY OF FILES

16 mm	.30 mm	.58 mm	greater than 1mm to about 3 mm	.25mm
16 mm	.35 mm	.63 mm	greater than 1 mm to about 3 mm	.25mm
16 mm	.40 mm	.68 mm	greater than 1 mm to about 3 mm	.25mm

SECOND PLURALITY OF FILES

16 mm	.45 mm	.73 mm	greater than 1 mm to about 3 mm	.35mm
16 mm	.50 mm	.78 mm	greater than 1 mm to about 3 mm	.35mm
16 mm	.55 mm	.83 mm	greater than 1 mm to about 3 mm	.35mm
16 mm	.60 mm	.88 mm	greater than 1 mm to about 3 mm	.35mm
16 mm	.65 mm	.93 mm	greater than 1 mm to about 3 mm	.35mm
16 mm	.70 mm	.98 mm	greater than 1 mm to about 3 mm	.35mm
16 mm	.75 mm	1.03 mm	greater than 1 mm to about 3 mm	.35mm
16 mm	.80 mm	1.08 mm	greater than 1 mm to about 3 mm	.35mm



10.

For the reason that the bending force vector "A" is exerted on the pilot 15 and not on the fluted cutting edges 20 and 22 near the end 14 of the shank 12, the operator can selectively increase the curvature of the bend in the shank 12 by manually increasing the magnitude of the secondary force couple "B" at the handle 44 or powered handpiece to lead the file into a portion of the curved root canal which may have a diminishing radius of curvature.

Industrial Applicability:

Typically, the procedure for preparing a root canal for filling involves the use of a set of dental files having progressively larger diameters. The smallest dental file is used to cut an initial path through the tissue to be removed from the root canal and incrementally larger diameter files are used in succession to progressively remove more of the tissue until all of the dead or damaged tissue has been removed from the root canal. In this way, the dentist can check his progress after each cut.

With heretofore known dental files each success- ingly larger dental file does not necessarily follow the curvature of the previously cut path because, as discussed above, the bending forces are exerted on the cutting surfaces near the end of the file and therefore these files have a tendency to cut more deeply into the concave wall than into the convex wall of the curved root canal forming a ledge in the concave wall. Thus, each succeeding file further distorts the curved path of the curved root canal and enlarges the size of the ledge cut into the concave wall of the root canal. These files also progressively enlarge the bottom or apical foramen of the root canal.

Using the set of files 10 of the present invention, there is less danger of forming a ledge in the concave wall of the root canal, and of enlarging the apical foramen of the root canal.

FIGURE 8 is an exaggerated diagrammatic illustration of a tooth root canal 48 after the set of files of the present invention have been used. For the reasons previously mentioned, the first plurality of files will follow the path of the curved root canal. The apical foramen "E" is undamaged because, in



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about 95% of the cases, it is about .30 mm in diameter. Therefore, the pilot 15 of the first plurality of files of the set, being preferably .25 mm in diameter, will not enlarge the apical foramen. The area denoted as the numeral 60 is that length of the root canal worked or cleaned by the first plurality of files of the set and corresponds in diameter to the diameter of the shank 12 about 1 mm above the tapered end 14 of the largest file 10 of the first plurality of files, or about .40 mm. The area denoted as the numeral 62 is that length of the root canal worked or cleaned by the second plurality of files of the set. Because the pilot 15 of the second plurality of files is larger in diameter than the apical foramen of the root canal, the pilot 15 of the second plurality of files will abut the bottom of the region 60 worked by the first plurality of files. Thus, the second plurality of files is prevented from penetrating and enlarging the apical foramen "E" of the root canal. Also, because the pilot 15 of the second plurality of files is only somewhat smaller in diameter than that of the worked length 60, the pilot 15 of the second plurality of files will easily move into the previously worked length 60, but will not move a significant distance laterally of the worked length 60. Therefore, the pilot 15 of the second plurality of files will guide the files into the worked length 60 faithfully following the path of the first plurality of files.

It should be understood that dental files tapering to a point having cutting surfaces extending to the point can be used in conjunction with the set of files 10 of the present invention if so desired. For example, the initial step of cleaning a root canal could be made with such file having a diameter near the pointed end of less than .30 mm, and the set of files 10 of the present invention used to perform the subsequent steps of cleaning the root canal.



12.

The Claims:

1. A dental file having a shank tapered along at least part of its length and having cutting means formed in at least a portion of the tapered length of the shank, characterized by the provision of a generally cylindrical, non-cutting pilot having a generally blunt end formed at and projecting coaxially from the tapered end of the shank, and having a length from greater than about 1.0 mm to about 3.0 mm.

2. A set of dental files in accordance with Claim 1 in which the files of the set have tapered shanks which increase in diameter from one file to the next larger file in the set and the diameter of the pilot being substantially the same for each file in the set.

3. The set of dental files of Claim 2, wherein the pilot of each file of the set has a smaller diameter than the diameter of the tapered shank of the smallest file of the set measured at about 1 mm above the tapered end of the shank.

4. The set of dental files of Claim 2, comprising: a first plurality of dental files having said tapered shanks which incrementally increase in diameter from one file to the next larger file of the first plurality of files, each file of said first plurality of files having a pilot of substantially the same diameter and corresponding to the pilot dimensioned for the smallest file of the set; and, a second plurality of dental files having said tapered shanks which incrementally increase in diameter from one file to the next larger file of the second plurality of files, the smallest file of said second plurality of files having a shank diameter larger than the largest file of said first plurality of files, each file of said second plurality of files having a pilot of substantially the same diameter as the other of the files of said second plurality of files, said diameter being smaller than the diameter of the shank of the largest dental file of said first plurality of files as measured about 1 mm from the tapered end of the largest file of said first plurality of files.

5. The set of dental files of Claim 4, wherein the length of said pilot of each file of said second plurality



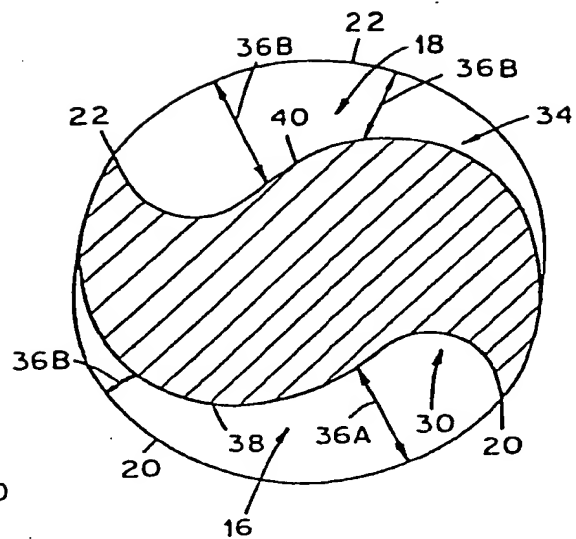
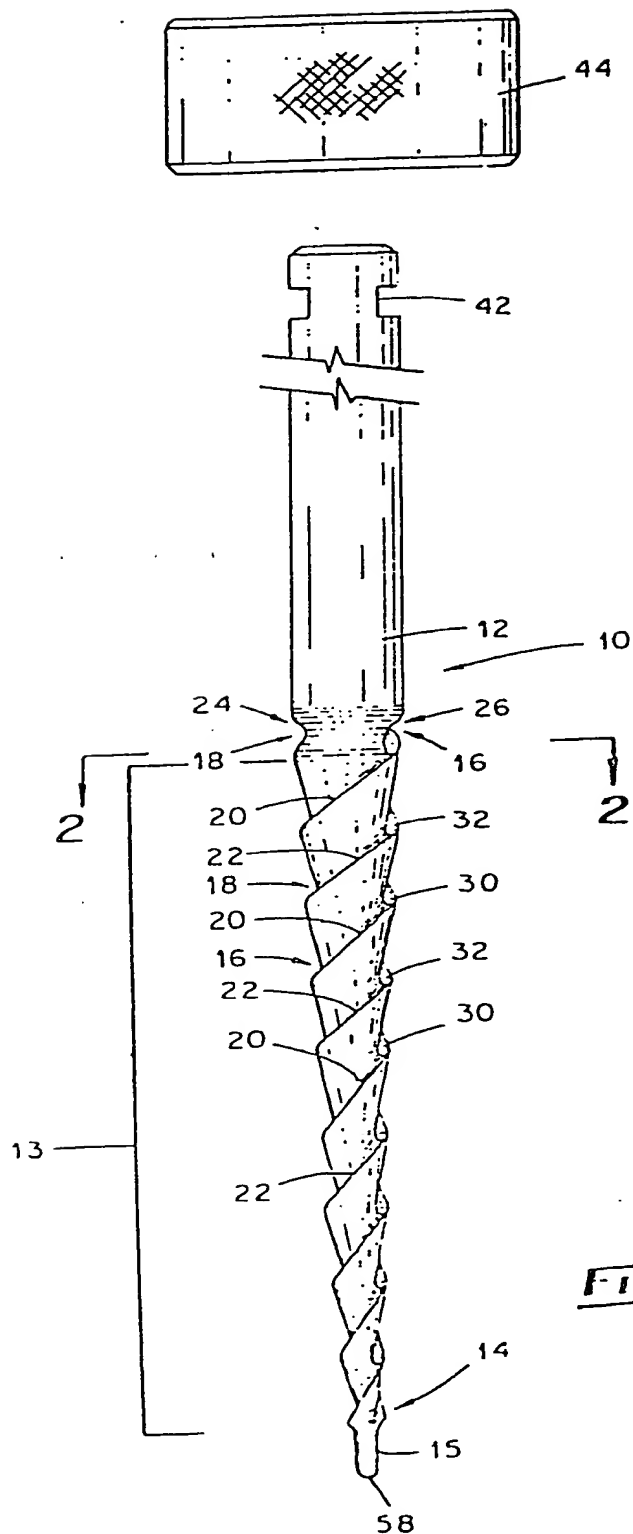
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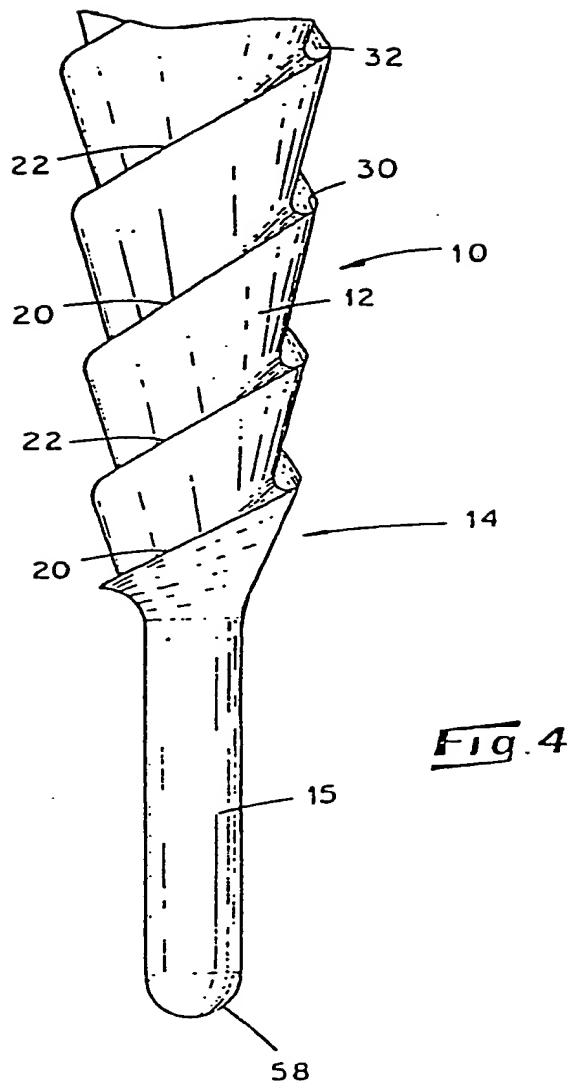
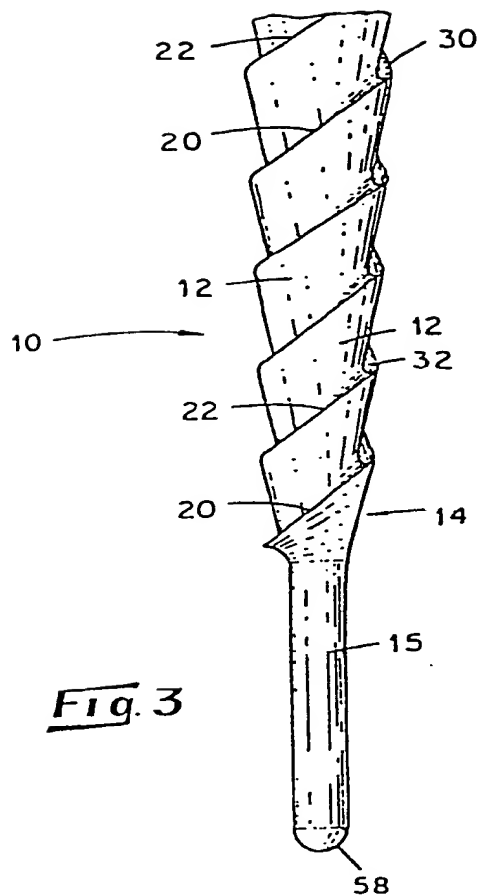
of files is substantially the same as the length of said pilot of each file of said first plurality of files.

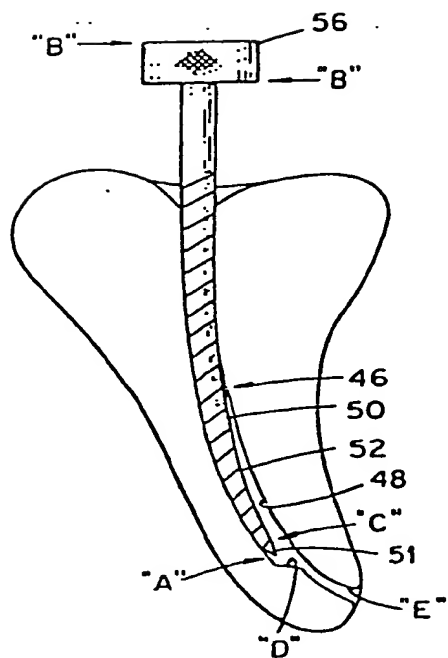
6. The dental file of Claim 1 wherein the diameter of the pilot is from about 0.25 mm to about 0.35 mm.



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Prior Art
Fig. 5

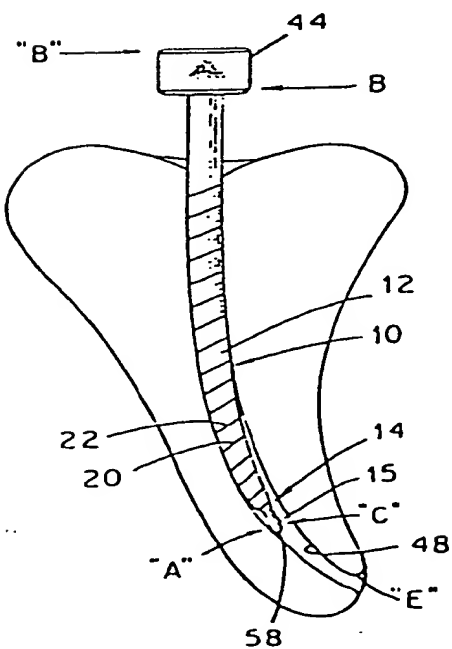


Fig. 6



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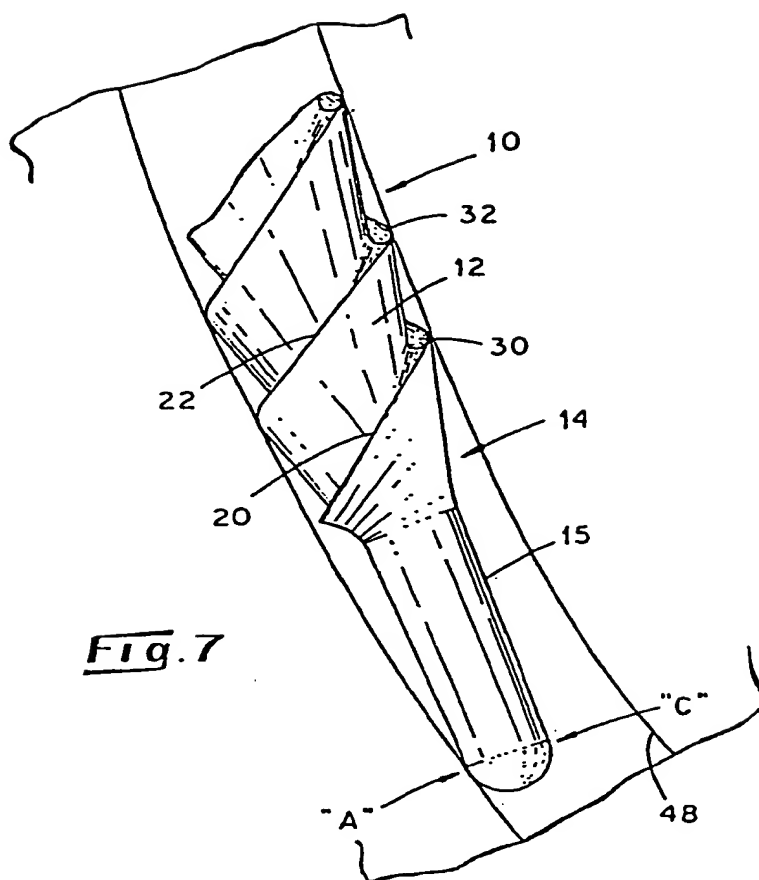


Fig. 7

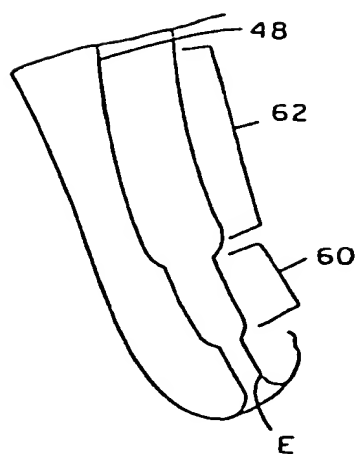


Fig. 8



INTERNATIONAL SEARCH REPORT

International Application No PCT/US81/01016

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) *		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int. Cl. ³	A61C	5/02
U.S. Cl.	433/102	
II. FIELDS SEARCHED		
Minimum Documentation Searched *		
Classification System	Classification Symbols	
U.S.	433/102 408/714 407/12,13	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched *		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴		
Category *	Citation of Document, ¹⁵ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸
X	US,A, 636,359, Published 07 November 1899 SCHULTZ	1-6
X	US,A, 1,307,446, Published 24 June 1919 KERR	1-6
X	US,A,4,165,562, Published 28 August 1979 SARFZTTI	1-6
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IV. CERTIFICATION		
Date of the Actual Completion of the International Search ¹	Date of Mailing of this International Search Report ²	
27 October 1981	30 OCT 1981	
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